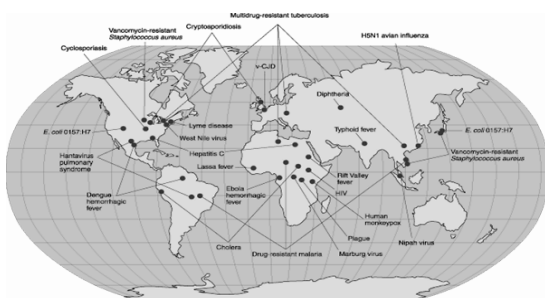


VACCINE LAW 101: Cost, Access & Delivery The Role of State Government

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June 12, 2006

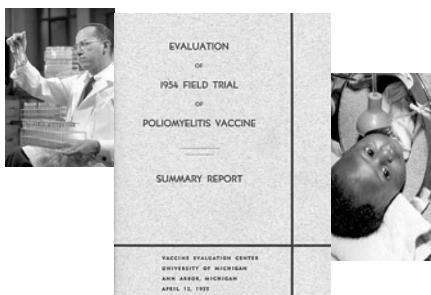
Vaccine Preventable Diseases

www3.niaid.nih.gov/.../0/emerging_diseases1.gif

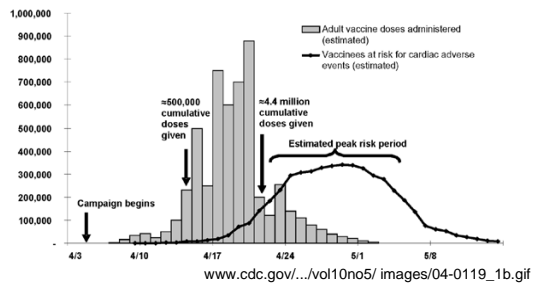


Partners: Federal-State-Private

(CDC and University of Michigan)



Smallpox-NYC 1947-Local



State's role – Procurement, Insurance, Administration, Coverage



State Support of Vaccination Programs

- Procure: Cooperative purchasing agreements
 - Distribution networks and clinics
- Insure: State insurance laws
 - Mandated benefits for State regulated plans
 - Medicaid program expansion – CHIP
- Administer: State “scope of practice” laws
 - Determine who authorized to administer
- Cover: Mandated vaccination requirements
 - Words matter

Public Health Law Practice: Evaluating Mandatory Vaccination

Statutes

- Goal 1 – vaccination statute?
- Goal 2 – mandatory language?
- Goal 3 – coverage not mere offer?
- Goal 4 – ages covered?
- Goal 5 – accessible providers?
- Goal 6 – “hard / soft” exemption process?
- Goal 7 – standards for emergencies?

State Role 1: Procurement



Vaccine for Children Program Seattle Washington

“Vaccines for Children was established in 1993 to remove the barriers of cost and access to attaining childhood immunizations. The program is funded by the [CDC] and the State of Washington, and supplies vaccines to providers across the state. Almost 95% of public and private immunization providers in King County are currently enrolled. All children from birth up to the 19th birthday are eligible....”

Cooperative Purchasing Agreements

- **Welcome to the Minnesota Multi-State Contracting Alliance for Pharmacy (MMCAP) web site.**
- MMCAP is a voluntary group purchasing organization operated by the State of Minnesota serving government-authorized healthcare facilities. The goal of MMCAP is to provide member organizations the combined purchasing power to receive the best prices available for pharmaceuticals, hospital supplies, and related products.

Minnesota Multi-State – Flu vaccine

- MMCAP sincerely apologizes for any inconvenience the prebooking process may have caused members. Although it was anticipated that supplies would dwindle quickly, no one anticipated the volume of calls Sanofi Pasteur received. The company was overwhelmed when it received over 400,000 attempted calls in the first 30 minutes (this information is from AT&T). All Sanofi Pasteur vaccine was distributed on a first-come-first-served basis.

Sanofi Pasteur can only produce 50 million doses (about 40 percent of the United State's needs). It cannot supply all influenza vaccine to the nation and given the unpredictability and vulnerability of the production process it is best to have several different manufacturers.

State Role 2: Statutory Insurance Mandates – GWU Rosenbaum, et al.



Overview State Impact - 2003

- 160 million with ER sponsored health insurance
- 12 million with privately purchased insurance
- Of these 172 M, state insurance laws covered 100 million
- 33 states have state immun. Mandate
- 9 states without statutory mandate have a "universal" purchasing and distribution system

Statutory Epidemiology

Any statutory mandate?	33 yes – 18 no
Mandated coverage v. offer?	32 coverage – 2 offer
Patient classes covered?	Children 33 – adults 2
Specific benefit mandated?	ACIP 6 – AAP 6 – Appropriate / Regs
Level of patient cost sharing?	21 no deductible 13 no co payments
In network coverage only?	No state addresses

State Role 3: Defining Providers' "Scope of Practice"



www.whitehouse.gov/omb/budget/fy2006/hhs.html

How States Regulate Immunization Practice

- States define practice of medicine
- Immunizations constitute practice of medicine
- States regulate physician's ability to delegate medical duties
 - "Standing orders"
 - "Delegation agreements"

Five State Survey Finding (GA, NY, MA, OR, TX)

- All permit physician delegation of immunization practice
- Non-physicians granted limited statutory authority
 - MA: full practice by "prescriptive practice nurse"
- Broad variation in permissible "standing orders" and delegations
- Overall, physicians control scope and extent of state's immunization practice

Legislative Committee – Mark Up Meeting



Defining the General Scope of the Benefit Package

- A health benefit plan shall also provide that the health benefits applicable to children include coverage for immunization services up to the age of thirteen.
 - Colorado

Colorado Problem

- Which benefits covered?
- No coverage past age 13?



www.whitehouse.gov/omb/budget/fy2006/hhs.html

Others

- "... basic coverage for child wellness services for an insured child."
 - Georgia
- "...shall provide coverage for childhood immunizations."
 - New Mexico
- "Benefits do not need to be provided... for pediatric preventive care services ... offered free by the State...."
 - Rhode Island

Mandated Coverage v. Mandated Offer

- Every insurer shall provide insurance which covers benefits for the comprehensive care of children
 - California
- A plan that provides benefits for a family member shall provide an option to elect coverage for immunizations
 - Mississippi

Range of Immunizations Covered

- The minimum package of child wellness services shall cover at least: all visits and costs of childhood and adolescent immunizations recommended by the Advisory Committee on Immunization Practices of the CDC
 - Maryland

Other Statutory Ranges

- Appropriate immunizations in keeping with prevailing medical standards
 - Arkansas
- Coverage for preventive care services as recommended by the physician
 - District of Columbia
- Immunizations as prescribed by the Commissioner of Health
 - Virginia

Emergency issues



Emergency Vaccination Powers

- Locate supplies
- Control supplies
- Manage distribution
- Mandate vaccination
 - Quarantine alternative
- Liability and immunity
 - Going off label
- Create surge capacity
 - Scope of practice
 - Locations
 - Record keeping
- Set prices
 - Manage price gouging
- Pay fair compensation

Emergency Powers - Maryland

- The Secretary shall develop a process to license, certify or credential health care practitioners who may be needed to respond to a catastrophic health emergency
- The Governor may order any health care provider to participate in disease surveillance, treatment, and suppression efforts

Public Health Legal Analysis: State Vaccination Programs

- Not enough to purchase
 - Must have professionals available to deliver
 - Must have insurance policies that cover
- Not enough to mandate
 - Must determine which vaccines covered
 - Must establish ages covered
 - Must decide degree of cost shifting permitted
 - Must decide “hard or soft” exemption policy

Turning Point Model State Public Health Act: Section 5-109

- State may require vaccinations
- Require informed consent and use of licensed vaccine for valid purpose
- Broad authority to administer – doctors, pharmacists, registered nurses, paramedical personnel
- Provide certificates and maintain registry
- Childhood vaccines under ACIP
